

REMARKS

Claims 1-18, 22-26, and 30-41 constitute the pending claims in the present application. Claims 1 and 41 have been amended. Support for such amendment may be found throughout the specification and claims as originally filed, including for example, p. 13 ll. 13-21. No new matter has been added.

Amendment of the originally filed claims, or cancellation of any claims should in no way be construed as an acquiescence, narrowing, or surrender of any subject matter. The amendments are being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicants reserve the option to prosecute the originally filed claims further, or similar ones, in the instant or subsequently filed patent applications.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 1-14, 17, 22-24, 26, 32-33 and 39-41 stand rejected under 35 U.S.C §102(b) as being anticipated by U.S. Patent 2,676,961(the '961 patent). The Office Action states that “ '961 teaches a suspension intramuscular composition comprising about 30% (300,000 units in 1 ml) of procaine-penicillin by weight in peanut or sesame oil (see col. 4-5, Examples 3-4).” Solely to expedite prosecution and to clarify the claims, claims 1 and 41 have been amended to recite “**inorganic** salt of a caine analgesic.” The procaine-penicillin composition described in the '961 patent is not an inorganic salt of a caine analglesic agent, as recited in amended claim 1. Applicants assert that one of skill in the art would recognize that procaine-penicillin has significant structural and chemical differences and properties as compared to inorganic salts of caine analgesics, as evidenced at least in part by the Merck Index relied on by the Examiner. Applicants therefore respectfully request reconsideration and withdrawal of these rejections based on the disclosure of the '961 patent.

Claim Rejections under 35 U.S.C §103(a)

Claims 15-16, 18, 25, and 34-38 stand rejected under 35 U.S.C § 103(a) as being unpatentable over the '961 patent. Applicants respectfully submit that this reference, for the reasons discussed above, does not disclose all the limitations of the amended independent claims

on which these rejected claims depend. Nor does it suggest modifications of the teachings therein which would produce all limitations of the claimed invention. Accordingly, the Applicants respectfully request withdrawal of this rejection.

Claims 30-31 stand rejected under 35 U.S.C § 103(a) as being unpatentable over the '793 patent. The Office Action states that "[a]bsent evidence to the contrary, ... optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan."

As the Examiner knows, a particular parameter "must first be recognized as a result-effective variable, i.e. a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." M.P.E.P 2144.05 II. B. Applicants assert that the '793 patent does not recognize, for example, any advantage of a composition that includes a weight percent of a caine analgesic, e.g. at least 3% lidocaine HCl by weight of a flowable composition. In fact, the '793 patent indicates that the disclosed combination "eliminates the necessity of using potentially harmful cocaine or any of its derivatives, such as procaine." '793, col. 3 ll. 50-52.

Applicants assert that the '793 patent includes no teaching or suggestion of a composition wherein a salt of lidocaine comprises at least about 3% and no more than about 80% by weight of the flowable pharmaceutical composition, as recited in claim 1 and dependent claims 30-31. Accordingly, the Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-832-1000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this application be charged to **Deposit Account No. 06-1448, GPT-029.01.**

Respectfully submitted,
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